

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

Civil Action No.: 06-222 JJF

PUBLIC VERSION

**DEFENDANT IMPAX LABORATORIES, INC.'S BRIEF
IN SUPPORT OF ITS MOTION TO COMPEL RESPONSES TO
DEFENDANT'S REQUEST FOR ADMISSION NOS. 1-3, 31, 38, 50, 62, 67 AND 68**

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I. NATURE AND STAGE OF THE PROCEEDINGS

In this patent infringement suit, Wyeth alleges infringement of three patents relating to an extended release formulation of venlafaxine hydrochloride. Impax Laboratories, Inc. (“Impax”) is defending itself by asserting that (1) its products do not infringe the patents-in-suit, (2) the patents are invalid in view of the prior art and for failure to comply with 35 U.S.C. § 112, and (3) the patents are unenforceable due to inequitable conduct. Each issue requires detailed proofs. Accordingly, Impax continues to seek efficient discovery to facilitate such proofs and narrow the issues for trial. Impax has served two sets of Requests for Admission, and Wyeth has refused to respond or has provided inadequate responses to several requests seeking straightforward admissions of fact, prompting this motion.

II. FACTUAL BACKGROUND

A. Infringement And Patent Validity In View Of Prior Art Are Major Issues In This Case

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See Declaration of Mary B. Matterer in Support of Defendant’s Motion to Compel Responses to Request for Admission Nos. 1-3, 31, 38, 50, 62, 67 and 68 (“Matterer Decl.”), Ex. A at 5-8. Furthermore, Impax contends that one or more prior art compounds and references which were in the public domain render the asserted patent claims invalid as anticipated or obvious. See Matterer Decl., Ex. A at 11-15. In particular, Impax asserts that the Alza once-a-day extended release formulation of venlafaxine is invalidating prior art. See Matterer Decl., Ex. A at Amended Exhibit A. Moreover, all of the features of the purported “invention” of the patents-in-suit were well-known in the art of pharmaceutical formulations before Wyeth even filed its patent applications.

B. Impax Propounds Requests For Admission To Reduce Necessary Non-Infringement And Invalidity Proofs At Trial

Impax served its First Set of Requests for Admission on February 27, 2007. *See Matterer Decl., Ex. B.* Request for Admission No. 1 is a straightforward request asking Wyeth to admit to the genuineness and authorship of publicly available prior art references that Impax is asserting as prior art in this litigation. *See Matterer Decl., Ex. B at 2.* Request for Admission Nos. 2 and 3 ask Wyeth to admit that the prior art references were publicly available prior to two specific dates. *See Matterer Decl., Ex. B at 2.* The prior art that is the subject of these requests includes U.S. patents and scientific literature textbooks. Request Nos. 1-3 are reproduced below:

Request for Admission No. 1:

WYETH is requested to admit, separately for each reference listed in Exhibits A and B, that the document is a true and correct duplicate of the original document, accurately states and reflects the title, date, and authorship of said original, and is authentic within the meaning of Federal Rule of Evidence 901.

Request for Admission No. 2:

WYETH is requested to admit, separately for each reference listed in Exhibit A, that the reference was PUBLICLY AVAILABLE as of March 25, 1995.

Request for Admission No. 3:

WYETH is requested to admit, separately for each reference listed in Exhibit B, that the reference was PUBLICLY AVAILABLE as of November 5, 1996.

Matterer Decl., Ex. C.

On March 14, 2007 Impax served its Second Set of Requests for Admission. *See Matterer Decl., Ex. C.* Request No. 31 seeks an admission that a particular passage in the patents-in-suit regarding an explanation for critical failed formulations was added to the specification on November 5, 1997. *See Matterer Decl., Ex. C at 6.* To streamline the issues for Impax's non-infringement defenses, Request for Admission No. 38 seeks

an admission from Wyeth that the patents disclose a matrix of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose. *See Matterer Decl., Ex. C at 7.*

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See Matterer Decl., Ex. C at 12. As to the knowledge of one of skill in the art, Request No. 50 asks about combining active pharmaceutical ingredients with known extended release technology, and Request No. 62 relates to the ability of extended release formulations to eliminate peaks and troughs associated with multiple daily dosing. *See Matterer Decl., Ex. C at 9, 11.* These disputed Requests are reproduced below:

Request For Admission No. 31:

Admit that the passage at column 6, lines 6-35 of the '171 patent was added to the specification on November 5, 1997.

Request For Admission No. 38:

Admit that the PATENTS IN SUIT disclose a matrix of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose.

Request For Admission No. 50:

Admit that the idea to combine an active pharmaceutical compound with a known method of making an extended release formulation was known in the art of pharmaceutical formulation before March 25, 1995.

Request For Admission No. 62:

Admit that before March 25, 1995 it was known in the art of pharmaceutical formulation that a once-a-day extended release formulation of a drug eliminates the peaks and troughs associated with multiple daily dosing of an immediate release formulation of that drug.

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Matterer Decl., Ex. C.

C. Wyeth Provides Inadequate Responses Or Refuses To Respond To Impax's Requests

Wyeth's Responses to Impax's First Set of Requests for Admission were served on March 29, 2007 [*See* Matterer Decl., Ex. D], and Wyeth's Responses to Impax's Second Set of Request for Admission were served on April 13, 2006. *See* Matterer Decl., Ex. E. Several of these responses were either evasive, inadequate or completely non-responsive.

Request Nos. 1-3 are standard authentication/genuineness of document requests meant to save hours of trial time. Wyeth evasively responded that the prior art documents were what they "purport" to be and lodged multiple objections, including that it could not determine the truth of the assignment or ownership information on the patent documents. *See* Matterer Decl., Ex. D at, *e.g.*, 5, 6, 7, 8, 9, 10. Impax stated that Wyeth need not verify the authenticity of any assignments appearing on the face of the patent documents and agreed to provide the indicia of authenticity Wyeth has requested for journal articles. *See* Matterer Decl., Ex. F. Yet Wyeth still insists on forcing Impax to obtain certified copies of issued U.S. patents and will not authenticate copies of such documents obtained from the U.S. Patent & Trademark Office web site. *See* Matterer Decl., Ex. G at 2.

Wyeth's evasive and non-responsive answer to Request No. 31 admits that the text is "substantially similar" to what was added in the application filed on that date.

See Matterer Decl., Ex. E at 20-21. When Impax requested that Wyeth either amend its response to answer the request as posed or inform us in writing of any differences in the text between the application and the '171 patent,

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REDACTED See Matterer Decl., Ex. H at 2-3. Impax's due diligence reveals a trivial distinction between the two passages, but Wyeth has not informed Impax whether this is the basis for its evasive response.¹

Rather than admitting or denying that the patents-in-suit disclose a matrix, Wyeth's response to Request No. 38 only admits that a disclosed formulation contains venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose "intermixed." See Matterer Decl., Ex. E at 25. After Impax challenged the sufficiency of this response,

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See Matterer Decl., Ex. H at 3. It is true that the request using the phrase "matrix of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose" indicates that the drug is in the matrix, and there is no reason Wyeth cannot provide a response to it.

Wyeth also failed to respond to Request for Admission Nos. 50 and 62. As discussed below, its objections that these requests call for a legal conclusion and expert opinion do not excuse Wyeth's failure to respond. It is proper to seek admissions

¹ Impax conducted a simple comparison of the text added in U.S.S.N. 08/964,328, filed on November 5, 1997, to the final text in U.S. Patent No. 6,274,171. The only discernable difference is that "hydroxypropylmethylcellulose" is written as one word at Column 6, line 11 in the '171 patent, whereas it is written as two words (i.e., "hydroxypropylmethyl cellulose") in the '328 application as filed. Thereafter, Impax asked Wyeth whether this distinction was the basis for Wyeth's qualified Response to Request for Admission No. 31 that the text is "substantially similar" rather than providing a simple admission. See Matterer Decl., Ex. J. Wyeth had not responded to this point when this brief was filed.

as to mixed questions of law and fact.² Furthermore, to the extent Wyeth can respond to these requests based on its corporate knowledge, it has an obligation to respond, irrespective of how an expert may opine on the matter.

Finally, Wyeth did not respond to Request Nos. 67 and 68 as posed. Instead of admitting or denying the requests as written,

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See Matterer Decl., Ex. E

at 46, 47.

Accordingly, Impax brings this motion. Impax respectfully requests that this Court order Wyeth to respond to Impax's Request for Admission Nos. 1-3, 31, 38, 50, 62, 67 and 68 within 10 days.

III. SUMMARY OF ARGUMENT

The Requests for Admission served by Impax are typical requests regarding issues that should not be the subject of laborious and time consuming testimony or proofs at trial. There is no reason they should not be readily admitted. As they stand now, Wyeth's Responses to Impax's Request for Admission Nos. 1-3, 31, 38, 50, 62, 67 and 68 would leave Impax with no choice but to expend judicial time and resources proving at trial straightforward fact issues within Wyeth's corporate knowledge. *See SIG Swiss Indus. Co. v. Fres-Co Sys., USA, Inc.*, 1993 U.S. Dist. LEXIS 6388 at *4 (E.D. Pa. Apr. 30, 1993) (*quoting Al-Jundi v. Rockefeller*, 91 F.R.D. 590, 593 (W.D.N.Y. 1981) ("Rule 36 RFAs serve the highly desirable purpose of eliminating the need for proof of issues upon trial")). Wyeth has either responded to the requests as it wished they were written, provided cynical and contradictory responses, or refused to respond at all. As discussed in detail below, Wyeth's responses are deficient and its objections without merit.

² *See Marchand v. Mercy Med. Ctr.*, 22 F.3d 933, 937, n.4 (9th Cir. 1994) ("Rule 36(a) permits requests for admission addressing questions of mixed law and fact").

IV. ARGUMENT

A. **Wyeth Should Respond To Request For Admission Nos. 1-3 And Impax Should Not Have To Obtain Certified Copies Of Patent Documents**

Request for Admission No. 1 asks Wyeth to admit to the genuineness and authorship of publicly available prior art references that Impax is asserting as prior art in this litigation. *See Matterer Decl.*, Ex. B at 2. Rather than providing a simple admission or denial with regard to the documents cited in this request, Wyeth provides the evasive response that each document “purports to be a copy” of the prior art reference. *See Matterer Decl.*, Ex. D at, *e.g.*, 5, 6, 7, 8, 9, 10. Requests for admission as to the genuineness of documents are commonplace and serve to simplify and expedite proceedings by removing issues from dispute. *See 7 MOORE’S FEDERAL PRACTICE & PROCEDURE* § 36.10[9] (2007) (“[r]equests for admission as to the genuineness of documents can be particularly useful in helping parties determine which documents that are to be introduced at trial will present foundational problems and which will not”).

Request for Admission Nos. 2 and 3 ask Wyeth to admit that the prior art references were publicly available prior to two specific dates. Wyeth contends that “the information reasonably available to Wyeth is insufficient to enable it to admit or deny whether” the documents were publicly available. *See Matterer Decl.*, Ex. D at, *e.g.*, 24.

Impax has agreed to provide journal articles with indicia of authenticity suitable to Wyeth.³ *See Matterer Decl.*, Ex. F. Impax has further agreed to narrow Requests 1-3 to the extent they seek admissions that the assignments listed on the U.S. and foreign patents and published applications are current. *See Matterer Decl.*, Ex. F. Nevertheless, with respect to patent documents, Wyeth has dug in its heels and still insists on certified

³ Wyeth has agreed to admit or deny with respect to journal articles if Impax provides to Wyeth the articles with cover page, table of contents and a reasonable indication of publication date. *See Matterer Decl.*, Ex. G at 2. Impax has agreed to this compromise. *See Matterer Decl.*, Ex. F.

copies. *See* Matterer Decl, Ex. G at 2. There is no reason Wyeth cannot stipulate to the authenticity of clean copies of such documents obtained from legitimate sources, such as the U.S. Patent & Trademark Office web site and its foreign counterparts.⁴ Impax believes this is unreasonable.

B. Wyeth Should Respond To Request For Admission No. 31 Or Explain The Basis For Its Suggestion That The Passages Are Different

Wyeth's response to this request and subsequent objections are pure gamesmanship intended to delay and waste time. This request seeks an admission that the passage at column 6, lines 6-35 of the '171 patent regarding Wyeth's explanation for critical formulation failures was added to the specification on November 5, 1997. *See* Matterer Decl, Ex. C at 6. As discussed above, Impax is struggling to pin down a definitive response or an explanation of any difference between the passage as filed in the U.S. Patent & Trademark Office and as it appears in the issued patents. Wyeth coyly hints at a difference by responding that the text is "substantially similar," but refuses to admit whether there is anything more than the trivial distinction of a chemical name written as one word versus two words. *See* Matterer Decl, Ex. E at 20-21, Ex. H at 2-3. Impax simply seeks a straightforward response to this request.

C. Wyeth Is Obligated To Provide A Response To Request For Admission No. 38 As It Is Written

Request for Admission No. 38 asks Wyeth to admit that the patents-in-suit disclose "a matrix of venlafaxine hydrochloride, microcrystalline cellulose and optionally, hydroxymethylcellulose. *See* Matterer Decl., Ex. C at 7. As discussed above, Wyeth's response only admits that a disclosed formulation contains venlafaxine hydrochloride, microcrystalline cellulose and hydroxymethylcellulose "intermixed" and venlafaxine hydrochloride "intermixed" with microcrystalline cellulose. *See* Matterer

⁴ Indeed, if Impax had to resort to certified copies, it would not need Wyeth to stipulate to their authenticity because they would be admissible under Federal Rule of Evidence 902(4). *See* FED. R. EVID. 902(4) (2007).

Decl., Ex. E at 25. This response ignores the key term “matrix,” which Impax purposely put in the request to support its non-infringement and invalidity arguments. The term “matrix” is also used in the specification of the patents-in-suit, so it is clear that Wyeth understands the term. Therefore, after receiving this deficient response, Impax urged Wyeth to respond to the request as written.

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Matterer Decl., Ex. H at 3. This is precisely why Impax drafted Request No. 38 this way – Impax seeks a yes or no response to the question of whether the patents disclose a matrix that includes venlafaxine. Wyeth has no legitimate basis for refusing to respond to the request as posed.

D. Request Nos. 50 And 62 Properly Seek Admissions Of Fact Or, At Most, Admissions As To Mixed Questions Of Law And Fact

These requests seek admissions regarding public domain knowledge prior to March 25, 1995, the earliest possible 35 U.S.C. § 102(b) date of the patents-in-suit for prior art purposes. Specifically, the requests ask Wyeth to admit that combining an active pharmaceutical compound with a known method of making an extended release formulation was known in the art, and that the capability of extended release formulations to eliminate the peaks and troughs associated with multiple daily dosing was also known. *See* Matterer Decl., Ex. C at 9, 11. It is well-recognized that the content of the prior art is a question of fact. *See Optivus Tech., Inc. v. Ion Beam Applications S.A.*, 469 F.3d 978, 984-85 (Fed. Cir. 2006) (an obviousness determination is based on underlying questions of fact such as “the scope and content of the prior art”). These fact issues are important to determining the validity of the patents as they tend to show that the claimed extended release formulation is obvious in view of the knowledge of persons having ordinary skill in the art. Moreover, these are fundamental and straightforward points regarding the state of the art of extended release pharmaceutical formulations that should not require trial time to establish.

Nevertheless, Wyeth has provided no response whatsoever to these requests. Wyeth's objections that Request No. 50 calls for a legal conclusion [*See Matterer Decl.*, Ex. E at 33],

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These requests do not ask Wyeth to admit that the claims are obvious or to make any legal conclusions about the legal effects of prior art knowledge. Rather, they only seek admissions as to the fact of such knowledge.⁵ At most, the requests may be mixed questions of law and fact, which are appropriate for requests for admission. *See Marchand v. Mercy Med. Ctr.*, 22 F.3d 933, 937, n.4 (9th Cir. 1994) ("Rule 36(a) permits requests for admission addressing questions of mixed law and fact"); *See also SIG Swiss Indus. Co.*, 1993 U.S. Dist. LEXIS 6388 at *4 ("[a]nother purpose of Rule 36 is to facilitate proof as to issues which cannot be eliminated from the case and any matter within the scope of Fed. R. Civ. P. 26(b) that relates to statements or opinions of fact or of the application of the law to facts").

E. Wyeth Should Respond To Request For Admission Nos. 67 And 68 As Written

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This request seeks a pure legal conclusion and implicates no underlying facts whatsoever, and is therefore very different from Impax's Request Nos. 50 and 62 regarding what factual knowledge was in the public domain prior to May 25, 1995.

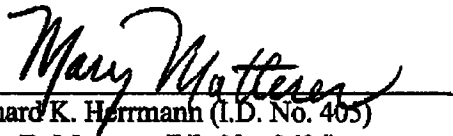
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Wyeth should be compelled to amend these non-responsive answers and provide appropriate responses to these requests as written.

V. CONCLUSION

For the foregoing reasons, Impax respectfully requests that the Court grant its motion to compel responses to Request for Admission Nos. 1-3, 31, 38, 50, 62, 67 and 68 within 10 days.

Dated: May 9, 2007


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CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of May, 2007, I electronically filed the foregoing document, **REDACTED VERSION OF DEFENDANT IMPAX LABORATORIES, INC.'S BRIEF IN SUPPORT OF ITS MOTION TO COMPEL RESPONSES TO DEFENDANT'S REQUEST FOR ADMISSION NOS. 1-3 31, 38, 50, 62, 67 AND 68**, with the Clerk of the Court using CM/ECF which sent notification of such filing to the following:

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